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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,990	01/14/2002	Kevin Leon Gaston	WIRO:016US	5151

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EXAMINER	
ANGELL, JON E	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/047,990	GASTON ET AL.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-47 are currently pending and are addressed herein.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-37, drawn to a method for inducing apoptosis in cells by administering an E2 protein to the cell, classified in class 514, subclass 2. (Note: the claims are drawn to administering an E2 protein or E2 protein derivative, including an E2 derivative that has a c-terminal deletion, including a deletion of the last 86 amino acids (eg, claim 35/6), or an E2 derivative wherein amino acids 296, 299 and 304 are missing. Each E2 molecule is structurally and functionally different, therefore group election of a single E2 molecule is required. (i.e. if applicants elect Group I they must specifically elect **a)** wild-type E2 protein, **b)** E2 protein derivative that has a c-terminal deletion, including a deletion of the last 86 amino acids, or **c)** an E2 derivative wherein amino acids 296, 299 and 304 are missing.)

II. Claims 1-37, drawn to a method for inducing apoptosis in cells by administering a nucleic acid encoding E2 protein to the cell, classified in class 514, subclass 2. (Note: the claims are drawn to administering a nucleic acid encoding an E2 protein or an E2 protein derivative, including an E2 derivative that has a c-terminal deletion, including a deletion of the last 86 amino acids (eg, claim 35/6), or an E2 derivative wherein amino acids 296, 299 and 304 are missing. Each E2 molecule is structurally and functionally different, therefore group election of a nucleic acid encoding a single E2 molecule is required. (i.e. if applicants elect

Group II they must specifically elect that the nucleic acid encodes either **a)** wild-type E2 protein, **b)** E2 protein derivative that has a c-terminal deletion, including a deletion of the last 86 amino acids, or **c)** an E2 derivative wherein amino acids 296, 299 and 304 are missing.)

III. Claim 38, drawn to a homodimer comprising a DNA-binding defective E2 derivative comprising an E2 amino acid sequence lacking C terminal portions of a native E2 sequence which includes an E2 protein wherein the last 82 amino acids are missing, classified in class 530, subclass 350.

IV. Claim 38, drawn to a homodimer comprising a DNA-binding defective E2 derivative comprising an E2 sequence in which amino acids 296, 299 and 304 of the native E2 protein are missing, classified in class 530, subclass 350.

V. Claim 39, drawn to a heterodimer comprising a DNA binding-defective derivative comprising an E2 amino acid sequence lacking C terminal portions of a native E2 sequence which includes an E2 protein wherein the last 82 amino acids are missing, classified in class 530 subclass 350.

VI. Claim 39, drawn to a heterodimer comprising a DNA-binding defective E2 derivative comprising an E2 sequence in which amino acids 296, 299 and 304 of the native E2 protein are missing, classified in class 530, subclass 350.

VII. Claims 40-47, drawn to a nucleic acid and vector comprising a nucleic acid encoding a modified E2 sequence, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions not disclosed as capable of use together and they have different modes of operation, different functions, or different effects because protein therapy involves administration of protein while nucleic acid therapy (i.e. gene therapy) involves administering nucleic acids. Nucleic acids and proteins are structurally and functionally distinct from each other therefore, the different groups utilize structurally and functionally different reagents that function differently.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different homodimers of polypeptides wherein the homodimmers are different structurally and functionally. Thererfore, they have different modes of operation, different functions, or different effects.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different heterodimer polypeptides wherein the heterodimers are different structurally and functionally. Thererfore, they have different modes of operation, different functions, or different effects.

Inventions I is related to Inventions III-VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for

using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product, such as any of the products of Inventions II-VI.

Invention II is related to Invention VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as a template for a PCR reaction; using the nucleic acid/vector to make the protein either in a cell for purification or in vitro; or, using the nucleic acids to make probes for hybridization assays.

Inventions I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects.

Invention II is unrelated to Inventions III-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for each Group is not the same as the searches required for the other Groups, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

With respect to the methods of inducing apoptosis in a cell, the following patentably distinct species of cell types are claimed and election of a single species is required:

1) PV negative cells
2) PV positive cells

upon election of one of the above cells, further election of one of the following distinct species is required:

A) p53 wild-type cells
B) p53 mutant cells
C) p53 related-gene positive cells

If C) is elected, further election of one of the following p53 related-genes is reuired:

a) p63
b) p73

With respect to the method of inducing apoptosis in a cell, the following patentably distinct species of treatments is claims and election of a single species is required:

1) E2 alone
2) E2 and p53
3) E2 and p53 and drugs
4) E2 and drugs

With respect to the different types of cells that apoptosis is induced in, applicants are required to elect a single species of cell type indicated in claim 15

With respect to cells infected with a virus, election of one of the following species of oncogenic virus is required (see claim 20):

1) oncogenic virus
2) retrovirus

Should applicants elect oncogenic virus, further election of a single species of one of the following oncogenic viruses is required:

A) HPV
B) Hepatits B
C) Epstein-Barr virus
D) Human T cell lymphotropic virus type 1
E) Human T cell lymphotropic virus type 2

Should applicants elect HPV above, further election of one of the following types of HPV is also required:

a) HPV16
b) HPV18

Should applicants elect the species retrovirus above, further election of a single species of retrovirus is also required:

a) HIV
b) HIV-related virus

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of each group as indicated above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicants are advised that the claims contain improper multiply dependent claims which should be corrected in response to the restriction requirement. It is noted that the Examiner did his best to properly restrict the claims in view of the improper multiple dependency and may need to adjust the restriction requirement upon amendment of the improper dependent claims. Furthermore, applicants are informed that claim 32 improperly depends on itself, but for restriction purposes only, the claim was considered to depend on claim 31. Claim 32 should be corrected and will be joined with the appropriate group after amendment of the claim.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-8656. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0756. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon Eric Angell, Ph.D.
Art unit 1635

DAV[illegible]NGUYEN
PRIM[illegible]EXAMINER